II. RESPONSE

A. Status of the Claims

Claims 111-116 were pending at the time of the Office Action ("The Action"). Claims 111-116 were rejected in the Action.

Claims 111-115 have been amended. No new matter was added by these amendments. Claim 116 has been canceled. Therefore, claims 111-115 are pending in the case. The specific grounds for rejection, and Applicants' response, are set out in detail below.

B. The Rejection Under 35 U.S.C. § 112, Second Paragraph, Is Overcome

Claims 111-116 were rejected as indefinite under 35 U.S.C. § 112. The Examiner stated that the rejection could be overcome by amending claim 111 to replace the term "encoding" with "comprising." To clarify the claim, Applicants have amended claim 111 as suggested by the Examiner. Applicants, therefore, request the withdrawal of this rejection.

C. The Rejection Under 35 U.S.C. § 102(a) Is Overcome

Claims 111 and 112 were rejected as being anticipated by Enari, *et al.*, NATURE Vol. 391:43-50. Applicants traverse the rejection.

To anticipate an invention, the prior art must teach every element of the claim. Enari, *et al.* does not teach all of the limitations of claims 111 and 112. Specifically, Enari, *et al.* does not teach SEQ ID NO:2, nor does it teach 23 contiguous amino acids of SEQ ID NO:2. Applicants, therefore, request that the rejection be withdrawn.

D. The Claims Are Supported by the Specification

Claims 111-115 were rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Applicants traverse this rejection.

1. Claim 111

Applicants submit that claim 111 is in condition for allowance. Current claim 111 reads "An isolated polypeptide comprising a DNA fragmentation factor, wherein the DNA fragmentation factor comprises SEQ ID NO:2." The Examiner has indicated that a claim of the scope of claim 111 would be allowable. The Action, p. 9, ln. 10-16.

Applicants, therefore, request that the rejection of claim 111 be withdrawn.

2. Claims 112-115

The Examiner argues that the claims lack an adequate written description because the claims describe a genus of polypeptides related to a disclosed human DFF40 DNA fragmentation factor, but the specification fails to describe the relevant identifying characteristics of the genus of polypeptides diverging at all but 20, 30, 50, 100 or more amino acid sequence positions from the sequence of SEQ ID NO:2. Thus, one of skill in the art would not be able to identify other, divergent DFF40 DNA fragmentation factors on the basis of the instant disclosure. Applicants traverse this rejection.

It is well-established that the inquiry of whether the written description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). In rejecting a claim under the written description requirement of 35 U.S.C. §112, first paragraph, the Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined in the claims. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90,96 (CCPA 1976). Thus, a requirement of this analysis is an analysis of the description of the invention defined by the claims.

Applicants assert that the Examiner, in making a written description rejection based on failure to recite relevant identifying characteristics of other divergent DFF40 DNA fragmentation

factor polypeptides in the specification, has failed to properly define the claimed invention. Claim 112 recites "An isolated polypeptide comprising 23 contiguous amino acids of SEQ ID NO:2." Accordingly, claims 112-115 pertain to polypeptides that comprise at least 23 contiguous amino acids of SEQ ID NO:2. The specification fully discloses SEQ ID NO:2. The Examiner, in requiring the structure, or other properties, of a genus of divergent DFF40 DNA fragmentation factor polypeptides to be disclosed in the specification in order to practice the claimed invention, has failed to properly define Applicants' claimed invention.

In particular, the Examiner appears to be misinterpreting the requirements of written description set forth in Uni*versity of California vs. Eli Lilly and Co.*, which requires that claims to genetic material require recitation of more than a mere function. *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) ("In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function.").

Applicants are not claiming a genus of DNA fragmentation factors described by function alone. Claims 112-115 are directed to polypeptides comprising at least 23 contiguous amino acids of SEQ ID NO:2. In contrast to the claims at issue in *Eli Lilly*, the present claims are supported by a description of the structure of the invention (*i.e.*, at least 23 contiguous amino acids of SEQ ID NO:2).

Applicants strongly assert that they are fully in compliance with the written description requirements set forth in *Eli Lilly* because the claimed polypeptides comprising at least 23 contiguous amino acids of SEQ ID NO:2 are fully supported by the specification, particularly since SEQ ID NO:2 is disclosed in the application. One of skill in the art would be able to

practice the claimed invention based on the existing disclosure without additional disclosure of other identifying characteristics of divergent DFF40 DNA fragmentation factor polypeptides.

In the present case, it is irrelevant whether additional sequences are attached to the claimed compositions as such additional sequences have not been claimed *per se*. If such a rejection were proper, "comprising" claim language could not be used with any claim, because in the case of nearly any composition or method it is possible to attach thereto some additional component of potentially unlimited size, which is itself not covered by the claim. What is relevant is that the claimed subject matter has been adequately described in a manner that reasonably conveys to one skilled in the art how to make and use the invention.

Applicants respectfully submit that the proper issue is not whether Applicants had in their possession a genus of DNA fragmentation factors, but rather whether they had possession of a polypeptide comprising 23 or more contiguous amino acids of SEQ ID NO:2, and the idea and means to make larger entities comprising those sequences. The specification would clearly allow one of skill in the art to recognize that Applicants were in possession of a polypeptide comprising 23 or more contiguous amino acids of SEQ ID NO:2. The 338 amino acids of SEQ ID NO:2 are disclosed in the specification. From looking at this sequence, one of skill in the art could easily recognize myriad polypeptides comprising 23 contiguous amino acids of SEQ ID NO:2. The claims, therefore, are supported by adequate written description in the specification.

3. Summary

For the reasons described above, claims 111-115 are supported by adequate written description in the specification. Applicants, therefore, request the withdrawal of this rejection.

E. The Claims Are Enabled

Claims 111-115 are rejected for lack of enablement under 35 U.S.C. § 112, first paragraph. The Examiner argues that the specification cannot support the breadth of the

proposed amino acid modifications to the sequence of SEQ ID NO:2, and provide a functional DNA fragmentation factor. Applicants traverse this rejection.

1. Claim 111

Applicants submit that current claim 111 is in condition for allowance. The Examiner has indicated that a claim of the scope of claim 111 would be allowable. The Action, p. 9, ln. 10-16. Applicants, therefore, request that the rejection of claim 111 be withdrawn.

2. Claims 112-115

The Examiner argues that "the specification is not enabling for the preparation of functioning DFF40 DNA fragmentation factors having amino acid sequences that diverge from the amino acid sequence of SEQ ID NO:2 by amino acid substitutions, deletions and insertions, or combinations thereof at as many as 94%...of the 338 amino acid positions within SEQ ID NO:2." The Action, paragraph bridging pages 4 and 5. Current claims 112-115, however, do not require that the polypeptide be a functional DNA fragmentation factor.

To be enabling within the meaning of 35 U.S.C. § 112, the application must contain a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984). By following the teachings in the specification, one of ordinary skill in the art would be able to make and use "an isolated polypeptide comprising 23 contiguous amino acids of SEQ ID NO:2." Polypeptides comprising 23 or more contiguous amino acids of SEQ ID NO:2 may be generated by, for example, recombinant DNA technology (see *e.g.*, p. 29, ln. 24-28), treatment of the amino acid sequence with proteolytic enzymes (see *e.g.*, p. 16, ln. 5-7), or peptide synthesis (p. 29, ln. 15-24). The claimed polypeptides are useful as, for example, antigens for the immunization of animals

relating to the production of antibodies as described in the specification at page 30, lines 7-17 and page 69, line 1 to page 74, line 16.

3. Summary

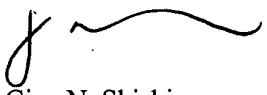
As described above, claims 111-115 are enabled by the specification. Applicants, therefore, request the withdrawal of this rejection.

F. Conclusion

Applicants submit that the claims are in condition for allowance, and an early indication to that effect is earnestly solicited.

The Examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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